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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,884	07/22/2003	Richard Harkins	51791AUSC1	1667

27586 7590 12/11/2006

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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,884	HARKINS ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *26-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-35 are pending.

2. Claims 26-35 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Claims 1-25 are under examination

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. This Office Action contains New Grounds of Rejections.

Rejections Withdrawn

6 The provisional rejection of claims 1-16 and 18-25 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-16 and 18-25 of copending Application No. 10/895,183 is withdrawn in view of the amendments to the claims filed 10/27/06 in copending application 10/895,183.

Objections/Rejections Maintained

7. The objection to the brief description of the drawings for Figure 9 as disclosing V_H_2m (SEQ ID NO:28), where Figure 9 discloses B_3M, V_H and Figure 10 as disclosing V_H_3m (SEQ ID NO:31), where Figure 10 discloses C_2m, V_H is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree. This has been fully considered but is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the objection.

8. The objection to the first line of the specification as needing to be updated with the U.S. Patent number for USSN 09/732,357, which is U.S. Patent 6,682,902 is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree, but does not provide an amendment to the specification and thus, the objection is maintained.

9. The objection to the disclosure for containing embedded hyperlinks and/or other form of browser-executable code is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree, but does not provide an amendment to the specification and thus, the objection is maintained.

10. The objection to the title of the invention as not being descriptive of the claimed invention is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree, but does not provide a new title that is clearly indicative of the invention to which the claims are directed and thus, the objection is maintained.

11. The objection to the specification for the use of the trademarks Phagescript®, Bluescript® Xenomouse™ and LifeSeq® (e.g., see pg. 26, line 13, pg. 28, line 11, pg. 34, line 14, pg. 47, line 3) is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree, but does not provide an amendment to the specification and thus, the objection is maintained.

12. The objection to claims 20-21 and 23-24 in the recitation "selected from a group consisting of...", which is not a proper Markush group is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree, but does not provide an amendment to the claims and thus, the objection is maintained.

13. The rejection of claims 1 and 3-25 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "an RG1 polypeptide" as the sole means of identifying the antibody specificity referred to in the claims is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree. This has been fully considered but is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the rejection.

14. The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the trademark/trade name Taxol™ is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree. This has been fully considered but is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the rejection.

15. The rejection of claims 1 and 3-25 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree. This has been fully considered but is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the rejection.

16. The rejection of claims 1, 3-8 and 17-25 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (i) an isolated human antibody and antigen-binding fragments thereof that specifically binds RG1 and conjugates of said human antibodies and (ii) an isolated human antibody and antigen-binding fragments thereof comprising a light chain variable region comprising the amino acid sequence of SEQ ID NO:26 or SEQ ID NO:29 or comprising a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:27, 28, 30 or 31, wherein the human antibody or antigen-binding fragments thereof specifically bind RG1, does not reasonably provide enablement for isolated human antibody *variants* and antigen-binding fragments thereof and an isolated human antibody and antigen-binding fragments thereof comprising a light chain variable region comprising an amino acid sequence having at least 80% sequence identity with SEQ ID NO:26 or SEQ ID NO:29 or comprising a heavy chain variable region comprising an amino acid sequence having at least 80% sequence identity with SEQ ID NO:27, 28, 30 or 31 is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree. This has been fully considered but is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the rejection.

17. The rejection of claims 1-2 and 15-17 under 35 U.S.C. 102(e) as being anticipated by Hastings et al (U.S. Patent 5,871,969, field 2/12/1997, cited on Ids filed 7/22/03) is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree. This has been fully considered but is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the rejection.

18. The rejection of claims 1-4 and 15-25 under 35 U.S.C. 103(a) as being unpatentable over Ali et al (US 2005/0147556 A1, priority to 10/19/1998) in view of Kucherlapati et al (U.S. Patent 6,150,584, filed 10/2/1996) and Devaux et al (U.S. Patent 6,824,780 B1, 10/29/1999) is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree. This has been fully considered but is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the rejection.

19. The provisional rejection of claim 17 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of copending Application No. 10/895,183 is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree. This has been fully considered but is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the rejection.

20. The rejection of claims 1-4 and 15-25 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-9 of U.S.

Patent No. 6,682,902 B2 in view of Kucherlapati et al (U.S. Patent 6,150,584, 10/2/1996) and Devaux et al (U.S. Patent 6,824,780 B1, 10/29/1999) is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree. This has been fully considered but is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the rejection.

21. The provisional rejection of claims 1-4 and 15-25 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-29, 31-34 and 44 of copending Application No. 10/616,279 in view of Kucherlapati et al (U.S. Patent 6,150,584, 10/2/1996) and Devaux et al (U.S. Patent 6,824,780 B1, 10/29/1999) is maintained.

The response filed 11/6/2006 states that applicants respectfully disagree. This has been fully considered but is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the rejection.

New Grounds of Rejection

22. Claims 1-16 and 18-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-6, 9, 11-15, 18-25, 37-39 and 41-43 of copending Application No. 10/895,183. Although the conflicting claims are not identical, they are not patentably distinct from each other.

It is noted that claim 17 remains provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of copending Application No. 10/895,183 (see item no. 19 above).

Prior to setting forth the rejection and for clarity of the record, it is noted that instant claims 1-16 and 18-25 were previously provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-16 and 18-25 of copending Application No. 10/895,183 (see item no. 6 above), however, the amendments to the claims filed 10/27/06 in copending Application No. 10/895,183 necessitated the instant provisional nonstatutory obviousness-type double patenting rejection.

Instant claims 1-16 and 18-25 are drawn to an isolated human antibody or antigen-binding fragment thereof that specifically binds to an epitope present in an RG1 polypeptide comprising the amino acid sequence of SEQ ID NO:2, wherein binding occurs with a K_D equal to or less than 1μM or 10nM and wherein the human antibody comprises a light chain variable region having an amino acid sequence at least 80% identical to SEQ ID NO:26 or 29 and/or comprises a heavy chain variable region having an amino acid sequence at least 80% identical to SEQ ID NO:27, 28, 30 or 31, or wherein the light chain variable region is encoded by a nucleotide sequence comprising SEQ ID NO:20 or 23 or wherein the heavy chain variable region is encoded by a nucleotide sequence comprising SEQ ID NO:21, 22, 24 or 25 and wherein said human antibody or antigen-binding fragment thereof is conjugated (i.e., immunconjugate) to a therapeutic agent or a detectable marker, wherein the therapeutic agent is a cytotoxic agent including various toxins, chemotherapeutic agents and radioisotopes and the detectable marker is a radiolabel, an enzyme, a chromophore, or a fluorescer and wherein the therapeutic agent or detectable marker is conjugated via the chelator

cyclohexyl-DTPA or MX-DTPA. Further, the claims are drawn to an antibody which binds the same epitope as the epitope bound by the human antibody comprising the light chain variable region of SEQ ID NO:26 and a heavy chain variable region selected from SEQ ID NO:27 or 28, or the human antibody comprising the light chain variable region of SEQ ID NO:29 and a heavy chain variable region selected from SEQ ID NO:30 or 31.

Claims 5-6, 9, 11-15, 18-25, 37-39 and 41-43 of copending Application No. 10/895,183 are drawn to an isolated human antibody or fragment thereof wherein the antibody comprises a light chain variable region comprising an amino acid sequence of SEQ ID NO:26 or 29, or is encoded by a nucleotide sequence comprising SEQ ID NO:20 or 23, or wherein the human antibody or fragment thereof comprises a heavy chain variable region comprising an amino acid sequence of SEQ ID NO:27, 28, 30 or 31, or is encoded by a nucleotide sequence comprising SEQ ID NO:21, 22, 24 or 25, or wherein the human antibody or fragment thereof comprises a light chain variable region having the amino acid sequence of SEQ ID NO:26 and a heavy chain variable region having the amino acid sequence SEQ ID NO:27 or 28, or a light chain variable region having the amino acid sequence of SEQ ID NO:29 and a heavy chain variable region having the amino acid sequence SEQ ID NO:30 or 31 and wherein the human antibody is a monoclonal antibody, is a single-chain antibody/polypeptide that binds RG1 and wherein said human antibody or antigen-binding fragment thereof is conjugated (i.e., immunconjugate) to a therapeutic agent or a detectable marker, wherein the therapeutic agent is a cytotoxic agent selected from various toxins, chemotherapeutic agents and

radioisotopes and the detectable marker is a radiolabel, an enzyme, a chromophore, or a fluorescer and wherein the therapeutic agent or detectable marker is conjugated via the chelator cyclohexyl-DTPA or MX-DTPA. Further, the claims are drawn to an isolated human antibody or fragment thereof that binds RG1 of SEQ ID NO:2 and comprising the light chain CDR3 or CDRs of SEQ ID NO:26 or the heavy chain CDR3 or CDRs of SEQ ID NO:27 as well as an antibody that binds the same epitope as the as the epitope bound by the human antibody comprising the light chain variable region of SEQ ID NO:26 and a heavy chain variable region selected from SEQ ID NO:27 or 28 or the human antibody comprising the light chain variable region of SEQ ID NO:29 and a heavy chain variable region selected from SEQ ID NO:30 or 31.

Thus, claims 5-6, 9, 11-15, 18-25, 37-39 and 41-43 of copending Application No. 10/895,183 are drawn to antibody species disclosed as having an affinity (K_D) for RG1 of less than 1 μM, or less than 10 nM (e.g., Table 1 at pg. 54 of the specification in USSN 10/895,183) and comprising variable domain sequences that are identical to the variable domain sequences of the antibodies claimed in the instant application. Therefore, claims 5-6, 9, 11-15, 18-25, 37-39 and 41-43 of copending Application No. 10/895,183 are drawn to antibody species that necessarily comprise the affinities and structures/sequences recited in the claims of the instant application and hence, read upon the antibodies claimed in the instant application, i.e., species anticipates the genus.

This is a provisional obviousness-type double patenting rejection.

Conclusion

23. No claim is allowed.

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827